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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,998	10/08/2003	Rudi Beyaert	2676-4554.1US	7433

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
06/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/680,998	BEYAERT ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *19,20 and 24* is/are allowed.

6)☒ Claim(s) *21 and 22* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *April 26, 2007* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/11/2007 has been entered.

The amendments to the claims filed on 5/11/2007 have been acknowledged.

Priority

This application is a DIV of 09/702,953 filed on 10/31/2000 now patent, which is a CON of PCT/BE99/00055 filed on 05/05/1999.

Claims

New claims 19-24 are pending and are under examination.

IDS

No new IDS was submitted.

Examiner's Note

Examiner offered to the Applicants an allowance of claims 19 and 20 (see below), on 26 of April 2007, but the Applicants rejected the proposed allowance.

Claims offered as allowed on April 26, 2007:

Claims 1-18 have been cancelled.
New claims:

***Claim 19**. A method for screening a compound for its ability to activate or suppress ABIN (A20-Binding Inhibitor of NF-kB activation) dependent NF-kB inhibition, said method comprising:*
a) combining a compound to be screened with a protein comprising ABIN amino acid consensus sequence of SEQ ID NO: 9 and having the ability to interact with protein A20,
b) detecting an interaction between said compound and said protein,
c) identifying compounds that interact with said protein,
d) obtaining a cell line with that nucleic acid sequence encoding protein A20, nucleic acid sequence encoding said ABIN consensus sequence protein, and an NF-kF dependent reporter gene,
e) administering at least one of TNF (tumor necrosis factor), IL-1 (interleukin-1), TPA (tissue plasminogen activator), TRADD (TNF receptor associated death domain), RIP (receptor interacting protein), TRAF2 (TNF receptor associated factor 2) to the cell line to induce activation of the NF-kB pathway,
f) administering the compound to said cell line, and
g) determining if the administration of the compound alters NF-kF dependent reporter gene expression,
wherein an increase in expression indicates that the compound activates ABIN dependent NF-kB inhibition and a decrease in expression indicates that the compound suppresses ABIN dependent NF-kB inhibition.
***Claim 20**. (Currently Amended) The method according to claim 19, wherein detecting an interaction between said compound and said protein is selected from the group consisting of a two-hybrid assay and a co-immunoprecipitation assay.*

Applicants Remarks in the RCE

Applicants stated that including protein A20 in the assay is an option but not a necessity, thus it is appropriate to have the protein A20 in a dependent claim. Further, experiments were conducted where protein A20 and ABIN were tested together where it shows that the individual suboptimal doses of protein A20 and ABIN were not sufficient to inhibit NF-kB activation (results are depicted in Fig. 5) but the combination of

suboptimal doses does inhibit NF-kB activation, and thus the protein A20 may be present in the claimed assay, but it is not required.

Also, Applicants stated that the invention works with any means for inducing activation of the NF-kB pathway, wherein the means is inhibitable by said ABIN consensus sequence.

Examiner considered the Applicants arguments when reviewing claims 19-24.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

"[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *>"The 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005).

In the instant invention, specifically claims 21 and 22, Applicants did not adequately disclose "a means for inducing activation of the NF-kB pathway, wherein the means is inhibitable by said ABIN consensus sequence protein" where used in a method of screening a compound for its ability to activate or suppress ABIN dependent NF-kB inhibition, because there can be many different structures/chemicals/factors, other than disclosed TNF, IL-1, TPA, RIP, TRAF2, that can achieve the same effect and purpose in the method claimed, and the Applicants are not entitled to all of these undisclosed means of inducing activation. Therefore, the written description requirement is not satisfied.

Claim 22 is included in this invention because it does not cure the deficiency of the independent claim 21.

Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening a compound for its ability to activate or suppress ABIN when TNF, IL-1, TPA, RIP, TRAF2 are administered to the cell line to induce activation of the NF-kB pathway, does not reasonably provide enablement for administering to the cell line any means for inducing activation of the NF-kB pathway, wherein the means is inhibitable by ABIN consensus sequence protein (see claim 21). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) eight factors should be addressed in determining enablement.

1.) The nature of the invention: the invention is a method of screening a compound for its ability to activate or suppress ABIN.

2.) The breadth of the claims: claim 21 is very broad because it refers to any means for inducing activation of the NF-kB pathway wherein the means is inhibitable by ABIN consensus sequence protein.

3.) The predictability or unpredictability of the art: / 7.) the art is unpredictable because there can be many other different means for inducing activation of the NF-kB pathway, that are different than disclosed TNF, IL-1, TPA, RIP, TRAF2.

4.) & 5.) The amount of direction or guidance presented:/The presence or absence of working examples: the working examples are presented only in regards to TNF, IL-1, TPA, RIP, TRAF2. No guidance is provided for other means that induce activation of the NF-kB pathway that are inhibitable by ABIN consensus sequence protein.

6.) The quantity of experimentation necessary: there is a large quantity of experimentation necessary to determine what means other than TNF, IL-1, TPA, RIP, TRAF2, can be used as being administered to a cell line to induce activation of NF-kB pathway, wherein the means are ihibitable by said ABIN consensus sequence protein.

8.) Level of skill in the art: the level of skill in this art is high.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by

the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue. Claim 22 is included in this invention because it does not cure the deficiency of the independent claim 21.

Objection to Claims

Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 19, 20, and 24 are allowable. Claim 23 is objected to. Claims 21 and 23 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER